

Application No. 09/871,823  
Amendment dated: March 15, 2004  
Reply to Office Action dated October 16, 2003

### **Remarks/Arguments**

#### **Amendments**

Applicant has amended Claims 1, 3, 4, 7-11, 13, 15-19, 21 and 23-25. New claims 26 and 27 have been introduced. Claims 1-27 are now in the application. Applicant submits that the independent claims remaining in the application read on all species disclosed, and thus are generic.

Claims 1 and 18 were amended to more clearly identify that the data handled by the card reader and the data acquisition unit in the system of the present invention are sensory data only and that analysis or evaluation of the sensory data for generation of an analysis result output to the user is carried out not in the diagnostic card reader but only in a general purpose computer separate and distinct from the diagnostic card reader.

Claims 3, 7, 8, 10, 15-19, 21 and 23-25 were amended in view of the amendments made to claim 1 to ensure consistent use of terminology throughout the claims. No new matter was introduced.

Claims 9, 11, 13 and 19 were slightly amended to improve their wording. No new matter was introduced.

The Examiner rejected claim 4 as being indefinite for defining features by using trademarks (PC, PCMCIA). Neither of the terms identified by the Examiner are registered trademarks or trade names, both terms being acronyms. Nevertheless, Applicant has amended claim 4 to replace the acronyms with the corresponding un-abbreviated terms. It is respectfully submitted that no new matter was introduced by way of this amendment, both acronyms being widely known and well understood.

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The Examiner objected to claims 11, 13-15, 17 and 21-25 as being dependent from a rejected base claim, but allowable if rewritten in independent form. Claim 21 has been rewritten in independent form as requested by the Examiner and now includes all the limitations of claim 1 from which it was originally dependent. Claims 22-25 are directly or indirectly dependent from claim 21. Thus, claims 21-25 as amended are believed in allowable form. Claims 11, 13-15 and 17 were not amended, since they are all directly or indirectly dependent from amended claim 1, which is now believed to define subject matter patentably distinguished from the art cited by the Examiner.

Applicant has introduced new claims 26 to 31. Claim 26 further defines the system of claim 1 as one including a card reader constructed to interface with different diagnostic cards respectively specific for different chemical species in the sample. This represents subject matter disclosed on pages 12 to 15 of the specification as originally filed. Thus, claim 26 is dependent from claim 1 and is fully supported by the specification as originally filed. Independent new claim 27 is similar to claim 21, as amended, and is directed to a card reader for use in a system as defined in general in claim 1. The reader is defined as including the connector, signal conversion and transmitter components of the card reader of claim 21. The transmitter component recited in claim 27 differs somewhat from the one defined in claim 21 in that it produces a transmittable digital signal rather than a signal for wireless transmission only. However, the subject matter of a transmitter component for the generation of different transmittable digital signals is disclosed on page 29 of the originally filed specification. Thus, new claim 27 is also fully supported in the specification as originally filed. New claims 28 to 31 are identical in wording to claims 22 to 25 as presented, but dependent from new claim 27 and, thus, are also fully supported in the originally filed application. Consequently, Applicant submits that no new search is required for the subject matter defined in new claims 26 to 31.

#### Arguments

The Examiner has rejected claims 1, 18, 2, 3, 5-10, 12 and 16 of the application as filed as being obvious over Jina (USP 6,066,504) in view of Ringrose (USP 4,149,405). From a study of its figures and description, it is apparent that the Jina reference teaches an electronic device and a test card for use therein which performs a coagulation or lysis assay of a blood

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sample. The device includes a housing adapted to receive the test card and including a power supply, connectors for connecting to electrodes on the test card, an analog to digital converter, a signal processor for analysis of the testing data and a display for output of the final test result. Interfacing with an external computer for downloading of the test results is possible through external ports. Ringrose discloses a method for measuring coagulation of a blood sample by measuring light reflected from the surface of the blood sample as the sample is vibrated. Changes in the viscosity of the sample caused by coagulation modify the reflection properties of the sample. Applicant submits that the claims as amended are patentable over the combined teachings of the Jina and Ringrose references.

Amended claim 1 defines a point-of-care blood measurement system for performing in vitro diagnostic chemical analysis of a sample, which system includes a diagnostic card reader for receiving a raw sensory signal from a diagnostic card and for providing an analog sensory signal directly related to the raw signal, a data acquisition unit for converting the analog sensory signal to a digital sensory signal and a general purpose computer separate and distinct from the diagnostic card reader for receiving and analysing the digital signal. Thus, the analysis and processing of the sensory signal into a diagnostic result output meaningful to the user is performed outside of and separate from the card reader. This is clearly distinct even from the combined teachings of Jina and Ringrose. When comparing the electronic device of Jina with the system defined in claim 1, it is readily apparent that the system of the invention is distinguished from the electronic device of Jina in that the functional unit performing the signal analysis (the general purpose computer) is separate and distinct from the card reader. Jina neither discloses nor suggests a system wherein the sensory signal processing is carried out in a distinct unit separate from the card reader. Jina discloses an electronic device wherein the sensory signal generated by the test card is picked up, processed and analyzed all in one single device combining the signal receiving and analyzing functions. Ringrose also neither discloses nor suggests a system wherein the sensory signal processing is carried out in a distinct unit separate from the card reader. Thus, Applicant submits that claim 1 is neither anticipated nor obvious in view of Jina and Ringrose and, thus, is patentable over Jina and Ringrose whether taken alone or in combination.

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Claim 18 has been correspondingly amended to clearly require that the general purpose computer for analyzing the digital sensory signal and producing an analysis result output is separate and distinct from the card reader. Thus, in view of the arguments presented above in relation to claim 1, Applicant respectfully submits that claim 18 is also neither anticipated nor obvious in view of Jina and Ringrose.

Claims 2, 3, 5, 6, 7, 8, 9, 10, 12 and 16 are all either directly or indirectly dependent from amended claim 1. Thus, they are narrower in scope than the independent claim. As such, Applicant submits that claims 2, 3, 5, 6, 7, 8, 9, 10, 12 and 16 are patentable over Jina and Ringrose whether taken alone or in combination. Consequently, Applicant respectfully requests that the rejection of claims 1, 18, 2, 3, 5, 6, 7, 8, 9, 10, 12 and 16 under 35 USC 103(a) be withdrawn.

In addition to the arguments presented above, Applicant respectfully submits that carrying out the signal analysis in a unit separate and distinct from the signal pick-up unit (the card reader) is much more than workshop improvement, since it creates a much more flexible and economical analysis system than the electronic devices disclosed in the art cited by the Examiner, and addresses significant disadvantages associated with prior art devices.

Conventional point-of-care blood analysis instrumentation is always in the form of a complete or nearly complete analyzer. It is capable on its own to deliver an analysis result output (for example a blood concentration value) rather than just a raw sensory signal output. Although the array of point-of-care instruments in a hospital-wide installation often communicates analysis results (blood concentration data) to a central, general-purpose computer, that computer is simply used for centralized collection and aggregation of analysis results and other patient relevant data, but not for sensory signal analysis. That is generally carried out within the conventional self-contained point-of-care analyzer instrumentation. The electronic device of Jani is a perfect example of that. Any connection of the device of Jani to a separate computer (as mentioned in columns 5 and 6) is solely for the purpose of downloading the results of the completed analysis ("test results") and not for analysis of the raw sensory signal in the computer. Jani teaches an independent electronic analysis device for reading the test

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card and generating the "test result" in the device itself. This is achieved by incorporation of complex and expensive hardware as well as all of the measurement software required for complete analysis. In other words, a complete, independent analyzer is provided for each measurement. This results in high operating cost for the device of Jani, especially when made as a disposable device, and even when the analyzer units are shared among numerous measurement locations. The device includes signal conditioning amplifiers and filters, a digitization circuit, a microprocessor and memory, all contained within the analyzer device. The microprocessor accepts the digitized sensor signals and uses the internal software to calculate concentration values, i.e. the final analysis result. The microprocessors and software also control the measurement process itself by controlling the temperature of the measurement chamber. They also control a display that outputs the calculated "test result". The microprocessor further controls the transmission of the test result, and possibly the measurement parameters to other devices such as a central data station.

In a typical hospital installation there are numerous point-of-care blood analyzer instruments connected to a central data station in which the point-of-care blood analysis results data is aggregated. That data is consolidated with other point-of-care data from other devices in the hospital's laboratory information system. The centralized data is used for archiving purposes, for patient billing as well as for quality assurance.

Different types of in-vitro blood tests have to be performed at each point-of-care location and most self-contained complete analyzers are normally designed to perform one type of test. For example, there may be an analyzer to measure glucose, another to measure blood gases and still others to measure cardiac markers and so on. This is also true for the device of Jani which is a self-contained complete analyzer specialized for blood coagulation analysis. As a result, an instrumented bedside is not only crowded but consists of significant and often duplicated hardware associated with significant capital cost. Thus, there exists a need for a low cost bedside instrumentation solution. That solution is achieved with the system of the present invention. By moving the sensory signal analysis functions into a general purpose computer adapted to process sensory signals by way of an internal software program, the complex and expensive components duplicated in each complete prior art analyzer are centralized in a

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single signal analysis unit. This significantly reduces not only the complexity of the system, but significantly reduces system cost and improves system flexibility, since only the test cards and possibly test card specific signal detection units, the card reader, need be modified for adaptation of the system to different types of analyses. Quality control of the system components is also facilitated by moving the signal analysis and the associated complex and expensive components into a separate and distinct signal analysis unit capable of handling a large variety of data originating from diagnostic cards for different types of blood tests. System maintenance is also facilitated, since new signal analysis software or software upgrades need only be loaded on the separate computer rather than on each self-contained analyzer.

Thus, the devices of the invention address a significant need in the field of healthcare by providing an improved point-of-care blood measurement system, that is less complex, much more flexible and more cost-effective and addresses problems of quality assurance in remote testing. Jina and Ringrose do neither disclose nor suggest the system structure presently claimed in this application which provides these advantages. More importantly, neither Jina nor Ringrose even acknowledge the problems addressed by the system of the present invention. In fact, Jina even teaches away from the solution provided by the present invention in teaching the inclusion of not only the test card reading function, but all analysis and output display functions in a single disposable device, which is a very costly and totally inflexible approach. Thus, Applicant respectfully submits that Jina and Ringrose, whether taken alone or in combination, cannot render the system presently claimed in this application obvious. Consequently, favorable consideration of the amended claims as presently presented is respectfully requested.

The Examiner rejected claim 4 under 35 U.S.C. 112 for use of trademarks. As described above, the acronyms used in claim 4 have been replaced with their corresponding expansions. It is submitted that the terms used in claim 4 clearly identify a type of data acquisition circuit. As a result, Applicant submits that the rejection to claim 4 under 35 U.S.C. 112 be withdrawn.


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A new dependent claim has been added, and there are presently 5 independent claims and 27 claims in total pending in the application. Thus, overall 2 independent claims and 4 dependent claims were added. The Commissioner is authorized to charge the requisite fees (2X\$43 plus 4X\$9) in the amount of \$122.00 to our firm's deposit account # 501593.

As the first deadline for response to the February 9, 2004 Office Action on the present application expired on May 9, 2004, a one month extension is being submitted in a separate letter of today's date.

Applicant submits that the application is now in condition for allowance and earnestly solicits action to that end.

Respectfully submitted,  
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